

REMARKS

Claims 1-3, 10-14, 20, 22-26, and 30-51 are currently pending in the application. Claims 1, 3, 10, 12, 14, 22, and 36-50 are amended. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

At the outset, Applicants would like to thank Examiner Hutson for taking the time to discuss the contents of this Office Action with Applicant's representative on December 19, 2006. The suggestions made by Examiner Hutson have been incorporated into this response.

Rejection of Claims 1, 3, 10-14, 20, and 22 Under 35 U.S.C. §112, Second Paragraph

The Office Action states that claims 1-3, 10-14, 20, and 22 are rejected under §112, second paragraph as being indefinite for failing to point out or distinctly claim the invention. In particular the Office Action rejects the claims on the grounds that the phrase "DNA polymerization activity of a DNA polymerase or reverse transcriptase" renders the claims indefinite. While not acquiescing to the rejection, Applicants have amended the claims to recite "5'-3' polymerization activity of a DNA polymerase or reverse transcriptase."

It is well settled law that the primary purpose of the definiteness requirement under §112, second paragraph, is to ensure that the scope of the claim is clear so that the public is informed of the boundaries of what constitutes infringement of the patent (MPEP 2173). This primary question is whether the claims are clear, not whether "more suitable language or modes of expression are available" (MPEP 2173.02). As amended the claims recite a first enzyme having 5'-3' polymerization activity of a DNA polymerase or reverse transcriptase. It is well known in the art, and described in the specification that polynucleotide polymerases catalyze the polymerization of nucleotides generally initiating synthesis at the 3' end of the primer and proceeding toward the 5' end of the template strand (Page 9). Both DNA polymerase and reverse transcriptases are known to have 5'-3' polymerization activity; that is, they can catalyze the 5'-3' polymerization of a new nucleic acid strand.

The metes and bounds of the claims is clear. Enzymes that fall under the claims are those that have the 5'-3' polymerization activity that is possessed by either a DNA polymerase or

reverse transcriptase. There is no ambiguity as to what is encompassed by this claim limitation. In addition, during the examiner interview of December 19, 2006, Applicants proposed the current claim language with respect to 5'-3' polymerization activity, and Examiner Hutson indicated that this amendment should be sufficient to overcome the rejection.

Applicants accordingly request that the rejections be reconsidered and withdrawn.

Rejection of Claims 1-3, 10-14, 20, 22, 36-39, 40-43, 44-47, and 48-51 Under 35 U.S.C. §112, First Paragraph

Written Description

The Office Action states that claims 1-3, 10-14, 20, 22, 36-39, 40-43, 44-47, and 48-51 under §112, first paragraph for allegedly failing to comply with the written description requirement. The Office Action states that the claims relate to a first enzyme that comprises "a DNA polymerization activity," but that such activity may include activities in addition to "DNA polymerization activity itself," such as DNA binding activity, dNTP binding activity, helicase activity, etc. The Office Action concludes that Applicants have not adequately described those enzymes that comprise the breadth of those activities. Applicants respectfully traverse the rejection.

As amended, the claims recite a first enzyme comprising "5'-3' polymerization activity of a DNA polymerase or reverse transcriptase," thus, clarifying that the activity possessed by the claimed enzyme is the DNA polymerization activity itself. The specification teaches (Page 1) that all DNA polymerases possess 5'-3' DNA polymerization activity and, further, specifically teaches over 30 examples of enzymes that possess the 5'-3' DNA polymerization activity of a DNA polymerase or reverse transcriptase.

Based on the disclosure in the specification and state of the art at the time the instant application was filed, Applicants have demonstrated that they were in possession of the invention recited in the amended claims and, accordingly, request that the rejection be reconsidered and withdrawn.

Enablement

The Office Action also states that the claims are rejected for lack of enablement. The Office action states that the claims are not enabled for a mutant Pfu DNA polymerase comprising one or more mutations at the recited positions.

Without acquiescing to the rejection, and solely for the purpose of expediting prosecution, Applicants have amended the claims to recite a “Pfu DNA polymerase consisting of an amino acid substitution at an amino acid position selected from the group consisting of” the specified sites of mutation. As amended, the claims no longer encompass amino acid substitutions in a Pfu DNA polymerase other than at the specified amino acid positions. The Office Action acknowledges that the specification is enabling for a Pfu DNA polymerase consisting of mutations at the specified locations.

The Office Action also states that the specification is only enabling for a Pfu DNA polymerase of SEQ ID NO: 19 consisting of the recited mutations. The specification, however, provides sufficient teachings, when considered with the knowledge in the art, of Pfu DNA polymerases, such that Applicants should not need to include reference to a particular Pfu sequence in the claims. For example, the specification teaches on page 16, that the amino acid sequence of Pfu DNA polymerase can be accessed in the Swissprot database at accession number P80061. The specification also teaches on page 25, that the structure of Pfu DNA polymerase is taught in four specifically referenced issued U.S. patents (incorporated by reference). Applicants have compared the Pfu sequences taught in accession number P80061, as well as the four patent references, and note that the Pfu DNA polymerase sequence taught in each is the same. Thus, at the time the instant invention was filed, the sequence of Pfu DNA polymerase was sufficiently well known such that reference only to a Pfu DNA polymerase would permit one of skill in the art to make and use the claimed invention without undue experimentation, and without needing a specific reference in the claim to a particular Pfu sequence.

Thus, as amended, one of skill in the art would be able to practice the claimed invention without the need to resort to any undue experimentation and, accordingly, Applicants request that the rejection be reconsidered and withdrawn.

Rejection of Claims 1-3, 10-14, 20, 22, and 36-51 for Obviousness-type Double Patenting

The Office Action states that claims 1-3, 10-14, 20, 22, and 36-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-70 and 75-87 of USSN 10/079,241. Without acquiescing to the rejection, Applicants intend to overcome this rejection by providing a Terminal Disclaimer in the instant case upon the notification of allowable claims.

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

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